

REMARKS

The Office Action mailed August 27, 2008 has been received and reviewed. All claims stand rejected. The claims are to be amended as previously set forth. All amendments and claim cancellations are made without prejudice or disclaimer. Support for new claims 22-24 and the amendments to claims 1 and 6 may be found throughout the Specification and, for example, at Example 1, Table 3. No new matter has been presented. Reconsideration is respectfully requested.

A. Rejections under 35 U.S.C. § 103

Claims 1-21 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over European Patent No. 0412849A to Willis et al. (“Willis”) in view of WO 01/11963 to Snyder et al. (“Snyder”). The rejection of claim 21 is moot since applicants have canceled claim 21. Applicants respectfully traverse the remaining rejections.

A framework for applying the statutory language of §103 is set out in *Graham v. John Deere Co. of Kansas City*, 383 U. S. 1 (1966):

“Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.”

Id., at 17-18.

To establish a *prima facie* case of obviousness, the prior art itself or “the inferences and creative steps that a person of ordinary skill in the art would [have] employ[ed]” at the time of the invention are to have taught or suggested the claim elements. Additionally, there must have been “a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements” in the manner claimed. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742, 167 L.Ed.2d 705, 75 USLW 4289, 82 USPQ2d 1385 (2007). “Often, it will be necessary for a [fact finder] to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background

knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed...To facilitate review, this analysis should be made explicit." *Id.* "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). Furthermore, to establish a *prima facie* case of obviousness there must have been a reasonable expectation of success. M.P.E.P. § 2143.02. Underlying the obvious determination is the fact that statutorily prohibited hindsight cannot be used. *KSR*, 127 82 USPQ2d at 1385.

Even if a *prima facie* case for obviousness were established by the Examiner (which applicants dispute in the instant case), *Graham* set forth a broad inquiry and invited those making decisions as to patentability, where appropriate, to look at any secondary considerations that would prove instructive. *Id.* Secondary considerations include unexpected results.

"[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known."

Id. at 1389.

"A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning. See *Graham*, 383 U.S. at 36 (warning against a 'temptation to read into the prior art the teachings of the invention in issue' and instructing courts to 'guard against slipping into the use of hindsight'" (quoting *Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co.*, 332 F. 2d 406, 412 (CA6 1964)))." *Id.* at 1397.

Applicants respectfully disagree that a *prima facie* case of obviousness has been established. Claim 1 is nonobvious because the references, either by themselves or in

combination, do not teach or suggest each and every element of claim 1. The references do not teach or suggest that the compounds of formula I and spinosyns could be combined in the manner claimed. Willis does not teach or suggest that the compounds of Willis could be used to control tick and flea infestations on an animal. Instead Willis teaches the use of pesticides in mice to kill the murine gastrointestinal nematode *Heligmosomoides polygyrus* as seen in Example 7A. While Willis is silent about fleas, the reference teaches that the compounds of Willis may be used to kill ticks not associated with a host. However, Willis does not indicate that the compounds of Willis could be administered to an animal to control tick infestations on the animal. As such, no reason exists that would have prompted a person of ordinary skill in the relevant field to combine the compounds of Willis with the spinosyns of Snyder because the compounds of Willis were not known to be effective against ticks and flea infestations on an animal. Willis is silent about spinosyns, flea infestations, and tick infestations of an animal. Furthermore, Snyder does not teach or suggest that spinosyns could be combined with the compounds of Formula I. Therefore, the combination of compounds of Formula I and spinosyns is not taught by the references.

However, to further clarify and expedite prosecution, claim 1 has been amended to include the recitation “wherein, at a spinosyn dosage of less than or equal to 30 mg/kg, the formulation is capable of achieving an efficacy of 90% in controlling flea and tick infestations in an animal 7 days after administration of the formulation as may be determined by a parasite assessment test.” Neither Willis, nor Snyder, teaches or suggests compounds which are capable of controlling flea and tick infestations in an animal, at a spinosyn dosage of less than or equal to 30 mg/kg, and at an efficacy of 90% or more against ticks 7 days after administration. While Willis is silent about spinosyns, Snyder does not teach or suggest the administration of one or more spinosyns at less than or equal to 30 mg/kg.

The smallest spinosyn dosage that Snyder teaches or suggests is 50 mg/kg. Snyder indicates that the effectiveness of spinosyns depends on the dosages used. *Snyder*, page 7, lines 7-9. As seen in Table 3 of Snyder, the efficacy of the 50 mg/kg dosage of spinosyn against ticks rapidly declines to only 67.8% nine days after the treatment. *Snyder*, page 13, Table 3. This study is consistent with applicant’s study where it was found that the efficacy of the 50 mg/kg dosage of spinosyns was reduced to 62.5% five days after the treatment and to 62.6% seven days

after the treatment. *Specification*, Example 3, Table 6. Both the Snyder study and applicant's study show that the efficacy of the 50 mg/kg spinosyn dosage is insufficient to prevent reinestation of the animal 5-9 days after the initial treatment. *Specification*, page 14, lines 21-23. However, claim 1 recites that at a 30 mg/kg dosage of one or more spinosyns one achieves an efficacy of 90% or more against ticks 7 days after administration if combined with one or more compounds of Formula I. As such, Snyder does not teach or suggest that tick and flea infestations could be controlled at an efficacy of 90% in an animal at a spinosyn dosage of less than or equal to 30 mg/kg seven days after administration. Willis does not cure the deficiencies of Snyder because Willis is silent about spinosyns, flea infestations, and tick infestations of an animal.

Additionally, applicants have shown that the formulation of claim 1 achieves unexpected results. The Examples describe that persistent activity against fleas and ticks is achieved by the combination of the compounds of Formula I and spinosyn. Spinosyns, by themselves, are known to lose effectiveness against ticks 5-9 days after the treatment. *Specification*, at Example 3 and *Snyder* at page 13, Table 3. However, the combination of the compounds of Formula I and spinosyns achieves 95.7% efficacy against ticks for at least 7 days after treatment. *Specification*, at Example 1, Table 3. Consequently, the formulation of claim 1 achieves the unexpected results of (1) effectiveness at lower dosages, (2) overall increased efficacy, and (3) increased efficacy at lower dosages. The unexpected results shown in the Examples are not reproduced by Willis or Snyder and, therefore, the combination of prior art elements does not lead a person of ordinary skill to a predictable result. This weighs against an obviousness determination.

Furthermore, claim 1 has been amended to include the recitation "wherein, at a spinosyn dosage of less than or equal to 30 mg/kg, the formulation is capable of achieving an efficacy of 90% in controlling flea and tick infestations in an animal 7 days after administration of the formulation as may be determined by a parasite assessment test." Claim 1 recites a new use for the combination of the compounds of Formula I and spinosyns and such use exhibits unexpected properties. While a new use for an otherwise obvious composition cannot render a claim to the composition patentable, any unexpected results accompanying such new use lead to patentable subject matter. *In re Sullivan*, 498 F.3d 1345, 1353 (Fed. Cir. 2007). In this case, claim 1 recites

a new use for the combination of the compounds of Formula I and spinosyn, namely, “wherein, at a spinosyn dosage of less than or equal to 30 mg/kg, the formulation is capable of achieving an efficacy of 90% in controlling flea and tick infestations in an animal 7 days after administration of the formulation as may be determined by a parasite assessment test.” At the time of the invention, compounds of Formula I were not known to be effective against ticks in an animal while spinosyns were not known to provide 90% or more efficacy against ticks at low dosages. The combination of these compounds and their new use in flea and tick control provides the unexpected result of long-term persistent tick control at low dosages. Therefore, as outlined in Sullivan, their combination is nonobvious.

Accordingly, applicants respectfully request the withdrawal of the 35 U.S.C. § 103(a) obviousness rejection of claim 1.

Independent claim 6 is nonobvious for at least the same reason as is claim 1. Applicants respectfully request the withdrawal of the 35 U.S.C. § 103(a) obviousness rejection of independent claim 6.

Claims 2-5 and 7-20 are nonobvious, inter alias, because they depend from nonobvious independent claims, namely claims 1 and 6.

Claim 5 is further allowable because Willis and Snyder do not teach or suggest the element of “wherein the ratio of the one or more compounds of formula (I) (and/or salts thereof) to the one or more spinosyns is from 1:10 to 10:1.” Willis and Snyder do not teach the combination of one or more compounds of formula (I) (and/or salts thereof) and one or more spinosyns and the references do not teach any ratios associated with such combination.

Claims 12, 14-16, and 18 are allowable for the same reasons as is claim 5.

Claims 8 and 19 are further allowable because Willis and Snyder do not teach or suggest the element of “wherein the one or more spinosyns and one or more compounds of formula (I) (and/or salts thereof) are administered simultaneously” and/or “wherein the spinosad and 5-chloro-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-(4,5-dicyano-1H-imidazol-2-yl)-3-methyl-1H-pyrazole (or salt thereof) are administered simultaneously.” Willis and Snyder do not teach the combination of one or more compounds of formula (I) (and/or salts thereof) and one or more

spinosyns and the references do not teach that the compounds are being administered simultaneously.

Claims 9 and 20 are further allowable because Willis and Snyder do not teach or suggest the element of “wherein the one or more spinosyns and one or more compounds of formula (I) (and/or salts thereof) are in a single preparation” or “wherein spinosad and 5-chloro-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-(4,5-dicyano-1H-imidazol-2-yl-3-methyl-1-H pyrazole (or salt thereof) are in a single preparation.” Willis and Snyder do not teach the combination of one or more compounds of formula (I) (and/or salts thereof) and one or more spinosyns and the references do not teach that the compounds are in a single preparation.

B. Rejections under 35 U.S.C. § 112, second paragraph

Claims 6-11 and 18-21 stand rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite. The rejection of claim 21 is moot since applicants have canceled claim 21. Applicants respectfully traverse the remaining rejections.

The Office alleges that claims 6-11 and 18-21 are indefinite because the host to whom the active compounds are administered is not set forth. *Office Action* mailed August 27, 2008, page 3.

To expedite prosecution, the claims have been amended herein to include the recitation “in an animal.” Accordingly, applicants respectfully request the withdrawal of the 35 U.S.C. § 112, second paragraph, indefiniteness rejection of claims 6-11 and 18-20.

Claim 21 stands rejected under 35 U.S.C. § 112, second paragraph, as assertedly being indefinite. The rejection of claim 21 is moot since applicants have canceled claim 21.

Accordingly, applicants respectfully request the withdrawal of the 35 U.S.C. § 112, second paragraph, indefiniteness rejection of claim 21.

C. Rejection under 35 U.S.C. § 101

Claim 21 stands rejected under 35 U.S.C. § 101 as assertedly including an improper definition of a process. The rejection of claim 21 is moot since applicants have canceled claim 21. Accordingly, applicants respectfully request the withdrawal of the 35 U.S.C. § 101 rejection

of claim 21.

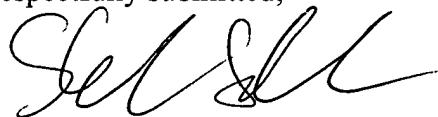
D. New Claims

New dependent claims 22-24 are also allowable over Willis and Snyder because the references do not teach or suggest each and every element of dependent claims 22-24. The references do not teach or suggest administering to the animal a reduced dosage of the formulation of claim 1 so as to maintain 90% efficacy against ticks for up to 7 days after the administration of the reduced dosages of the formulation. Instead, Snyder teaches a one-dose treatment with Spinosad at a higher dosage of 50 mg/kg which is insufficient to prevent reinestation with ticks. Furthermore, dependent claim 24 is allowable because Snyder does not teach or suggest administering a reduced dosage of the formulation (and/or salts thereof) of claim 1 to a reinfested animal since Snyder only teaches a one-dose treatment. Willis does not cure the deficiencies of Snyder because Willis does not administer any drugs to animals in order to treat flea and tick infestations.

CONCLUSION

Applicants believe the application is in condition for allowance, and a notice of allowance is kindly solicited. If, however, questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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